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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,879	05/25/2006	Scott M. Whitcup	17644(RET)	7311

51957 7590 07/30/2010

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EXAMINER	
FAY, ZOHREH A	

ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
07/30/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/580,879	WHITCUP ET AL.	
	Examiner	Art Unit	
	ZOHREH A. FAY	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 June 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *6-10 and 13-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 11 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/7/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-16 are pending in the instant application.

Claims 1-5, 11 and 12 are presented for examination.

The response to the restriction of March 30, 2010 has been received and entered.

Applicant elected macular degeneration with traverse for examination purpose.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 11 and 12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claimed invention is drawn to a method of reducing and/or preventing degeneration of photoreceptors using a retinoid compound having RAR beta and/or RAR gamma-selective agonist activity. The specification discloses examples of structures of some compounds within the scope of what is claimed. However there is no evidence that there is any per se structure/function relationship between the disclosed retinoid compounds having RAR beta or RAR gamma-selective agonist activity and any others that might be found using the claimed method. Structural identifying characteristics of group of a retinoid compound having RAR beta or RAR gamma-selective activity are not disclosed. The

claims are also drawn toe the treatment of unspecified disease. There is no evidence that the treatable diseases were known to the applicant. In the absence of understanding the disease to be treated, the artisan would not have accepted that applicant was in possession of the claimed method of use. Therefore the claimed invention is not supported by an adequate written description. To provide adequate written description an evidence of possession of the claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and /or chemical properties, Functional characteristics, structure/function correlation, or any combination thereof.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 11 and 12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating degeneration of photoreceptors, does not reasonably provide enablement for preventing. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The factors to be considered whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed. Cir.1988). Among these factors are:

1) The nature of the invention:

The claims are drawn to a method of reducing and/or preventing degeneration of photoreceptors using a retinoid compound having RAR beta or an RAR gamma-selective activity.

2) The state of the prior art:

The relative sill of those in the art is high, that of an MD or PHD. That factor is outweighed, however by the unpredictable nature of the art. The state of the art does not recognize that the prevention of degeneration of photoreceptors is accomplished easily. According the attached article by Cleveland Clinic, there are number of steps you can take to protect against AMD. Such article shows that the protection was done in patients with mild MAD in order to protect against the progression. There is no teaching of preventing the disease in healthy human.

3) The relative skill of those in the art:

The relative skill of those in the art is high.

4) The predictability or unpredictability of the art:

The unpredictability of pharmaceutical and chemical art is high.

5) The breath of the claims:

The claims are very broad. Since the instant specification provides no limiting definition of the term "prevention", the term will be interpreted expansively. The tem “prevention” might vary widely in meaning from “preventing” a disease from occurring to “preventing” it from progressing. Nor is the term limited by any time frame.

The claims are thus very broad insofar as they suggest that one will not experience the disease when taking the claimed agent; that should one get the disease , it will not worsen, or that following its treatment, it will not recur. While such "prevention" might theoretically be possible under stoically controlled laboratory conditions, as a practical matter it is nearly impossible to achieve the "real world" in which patient live.

6) The amount of direction or guidance provided:

The specification, including the working examples provides no direction for "preventing" degeneration of photoreceptors in the eye using the claimed compounds.

7) The presence or absence of working examples;

The examples set forth in the specification are drawn to the treatment of the claimed conditions. There are no examples set forth to demonstrate the "prevention" of the claimed conditions.

8) The quantity of experimentation necessary;

Applicant fails to provide guidance and information sufficient to allow the skilled artisan to ascertain how to "prevent" degeneration of photoreceptors of the eye. Absent such guidance and information, one skilled in the art would have to blindly and empirically experiment, with no reasonable prior expectation of success being present. Accordingly, the instant claims do not comply with the enablement requirement of 112 first paragraph, since to practice the claimed invention in its "full scope" a person of ordinary skill in the art would have to engage in undue experimentation with no assurance of success.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5, 11 and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Hughes et al. (US 2005/0009910).

Hughes et al. teach the use of retinoid agonists, tazarotenic acid and tazarotene for the treatment of macular degeneration. See claims 7, 8 and 13. The above reference makes clear that the claimed method of use is old and well known.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ZOHREH A. FAY whose telephone number is (571)272-0573. The examiner can normally be reached on Monday to Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fredrick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ZF
/Zohreh A Fay/
Primary Examiner, Art Unit 1612

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